

# Diluent Estradiol/Progesterone

**cobas®**

REF 03028542 122

2 x 22 mL

## English

### Intended use

Diluent Estradiol/Progesterone is used as a sample diluent in conjunction with the Elecsys Estradiol II, Elecsys Progesterone II and Elecsys Progesterone III assay.

### Summary

Dilution of samples is necessary when the analyte concentrations of the samples exceed the measuring range of the respective assay.

### Reagents - working solutions

Diluent Estradiol/Progesterone is labeled as Diluent Estradiol/Progesterone. 2 bottles each containing 22 mL

Contents: Pooled human serum obtained from male blood donors; preservative

Concentration of endogenous estradiol: < 45 pg/mL (< 165 pmol/L)

Concentration of endogenous progesterone: < 1 ng/mL (< 3.2 nmol/L)

### Precautions and warnings

For in vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:

Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:

Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:



### Warning

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

### Prevention:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P273 Avoid release to the environment.

P280 Wear protective gloves.

### Response:

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

### Disposal:

P501 Dispose of contents/container to an approved waste disposal plant.

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590

All human material should be considered potentially infectious. All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV. The testing methods use assays that have been approved by the FDA or that are in compliance with the legal rules applicable to placing in vitro diagnostic medical devices for human use on the market in the European Union.

However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level

of care as a patient specimen. In the event of exposure, the directives of the responsible health authorities should be followed.<sup>1,2</sup>

Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).

### Reagent handling

Diluent Estradiol/Progesterone is ready for use.

Bring to 20-25 °C before use.

Avoid contamination!

### Storage and stability

Store at 2-8 °C.

Stability:	
unopened at 2-8 °C	up to the stated expiration date
after opening at 2-8 °C	4 weeks

### Materials provided

- Diluent Estradiol/Progesterone

### Materials required (but not provided)

- MODULAR ANALYTICS E170 or **cobas e** immunoassay analyzers and assay reagents

See the appropriate assay Method Sheet and the operator's manual for additionally required materials.

### Assay

For analyte concentrations above the measuring range, see dilution recommendation in the respective Elecsys kit. Perform dilutions manually. Label diluted samples as such at the sample identification stage and analyze in the same way as undiluted samples.

### Elecsys test results

The endogenous analyte concentration (see "Reagents - working solutions") is not taken into account when dilutions are above the measuring range. Multiply the measured concentrations by the dilution factor.

The concentration in the diluted sample may not be less than the stated minimum concentration in the respective Elecsys assay.

### References

- Occupational Safety and Health Standards: Bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.
- Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

For further information, please refer to the appropriate operator's manual for the analyzer concerned, the respective application sheets, the product information and the Method Sheets of all necessary components (if available in your country).

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

### Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see [dialog.roche.com](http://dialog.roche.com) for definition of symbols used):

CONTENT	Contents of kit
SYSTEM	Analyzers/Instruments on which reagents can be used
REAGENT	Reagent
CALIBRATOR	Calibrator
→	Volume after reconstitution or mixing
GTIN	Global Trade Item Number

# Diluent Estradiol/Progesterone

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